

Appl. No. 09/230,195
Amdt. dated January 26, 2004
Amendment under 37 CFR 1.116 Expedited Procedure
Examining Group

PATENT

REMARKS

Please cancel claim 18 without prejudice to revival for subsequent prosecution in a continuation or divisional application. Claims 3, 36, and 39 were previously cancelled. Therefore, upon entry of the instant amendment, claims 1, 2, 4-17, 19-35, 37, 38, and 40-42 are under examination.

With entry of the instant amendment, claim 1 has been amended. The amendment adds no new matter and is supported in the application, e.g., at page 9, lines 28 through page 10, line 4.

For convenience, the rejections are addressed in the order presented in the Office Action mailed September 26, 2003.

Rejection under 35 U.S.C. § 112, first paragraph--enablement relating to the use of the claimed compositions

Claims 1, 3, 4-35, 41 and 42 were rejected as allegedly not enabled. The Examiner asserts that the "sole use of the claimed vectors as disclosed in the specification is for gene delivery and gene therapy" (page 3, lines 6-7 of the September 26, 2003 Office Action.) He then argues that one skilled in the art at the time of the invention would not know how to use the claimed vectors *in vivo* so as to provide a therapeutic effect for a particular disease or disorder in a subject. (page 4, lines 4-8 of the September 26, 2003 Office Action). Applicants respectfully traverse for reasons of record and further in view of the following.

Again, the Examiner's rejection is based the usefulness of the claimed composition. He argues that the claims are not enabled because the practitioner would not know how to use the vectors *in vivo*. The claims here are drawn to compositions, not methods. As Applicants have previously explained, the vectors can be used *in vitro* as well as *in vivo*. The rejection provides no evidence or reasoning as to why these vectors are not enabled for use *in vitro*. The MPEP uncategorically states, with respect to compositions, that "if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention" (MPEP § 2164.01(c)). Accordingly, the claims are enabled.

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Rejection under 35 U.S.C. § 112, first paragraph--enablement relating to pharmaceutical excipient

The Examiner contends that the claims are not enabled *in vivo* based on the recitation of the term "pharmaceutical excipient" in particular claims (claim 18). Although Applicants disagree for reasons of record, in order to expedite prosecution and simplify potential issues for appeal, Applicants have cancelled claim 18.

Rejection under 35 U.S.C. § 112, first paragraph--enablement relating to splice donor and splice acceptor subsequences

The Examiner contends that the term splice acceptor subsequence or splice donor subsequence encompasses sequences smaller than the consensus sequence of a splice acceptor or splice donor. The Examiner has provided no evidence or reasoning as to why one of skill in this advanced art would believe that the term "subsequence" applies to nonfunctional sequences that are smaller than the consensus sequence or would not be able to identify functional splice donor and splice acceptor sites. However, in order to expedite prosecution and simplify potential issues for appeal, Applicants have amended claim 1 to recite a splice donor site and a splice acceptor site.

In view of the foregoing, Applicants believe the claims are fully enabled and therefore respectfully request withdrawal of the rejection.

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CONCLUSION

Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

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